

AUG 25 2000

K002365

Attachment D

**SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
DATASCOPE'S REINFORCED PERCUTANEOUS CATHETER INTRODUCER**
(Prepared in accordance with 21 CFR Part 807.92)

A. GENERAL INFORMATION

Submitter: Datascope Corp.
Cardiac Assist Division
Address: 15 Law Drive
Fairfield, NJ 07004
Contact Person: JoAnn Wolf
Regulatory Affairs Associate

B. DEVICE INFORMATION

Generic Name: Catheter Introducer
Trade Name: Datascope's Reinforced Percutaneous Catheter
Introducer Set
Classification Name: Introducer, Catheters are classified under
21 CFR 870.1340

C. PREDICATE DEVICE INFORMATION

Datascope's Reinforced Percutaneous Catheter Introducer is substantially equivalent to the following marketed devices:

K980385 - Datascope's 8Fr. Intra Aortic Balloons (IABs) - with
Accessories (8Fr. Catheter Introducer), S/E 5/02/98

K980780 - Datascope's Percor STAT-DL 9.5 Fr, 24, 34 and 40cc IABs
with Alt "B" Membrane Material for Optional Sheathless
Insertion, S/E 5/29/98

K820834 - Datascope's 10 Fr. Percor Percutaneous Introducer with
Hemostasis Valve. S/E 3/26/82

K964814 - Bipore Accuflex Percutaneous Sheath Introducer, S/E
5/07/97

K984500 - Cordis Brite Tip Catheter Sheath Introducer System with
Guide Wire, S/E 12/23/98

D. DEVICE DESCRIPTION/INTENDED USE

Datascope's Reinforced Percutaneous Catheter Introducer Set is intended for the percutaneous introduction of Datascope's 8Fr. and 9.5 Fr. Intra-Aortic Balloon Catheters.

E. TECHNOLOGICAL CHARACTERISTICS

The difference in material grade and chemical composition has been demonstrated not to affect safety or efficacy of the device.

F. NON-CLINICAL TESTS

The results of in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed devices.

G. CLINICAL TESTS

There has been no clinical evaluation of the new device in the U.S.

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's Reinforced Percutaneous Catheter Introducer Set is considered substantially equivalent to Datascope's currently marketed catheter introducer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 25 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Datascope Corporation
Cardiac Assist Division
c/o Ms. JoAnn Wolf
Regulatory Affairs Associate
15 Law Drive
Fairfield, NJ 07004

Re: K002365
Datascope Reinforced Percutaneous Catheter Introducer Set
Regulatory Class: II (two)
Product Code: DYB
Dated: July 31, 2000
Received: August 3, 2000

Dear Ms. Wolf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

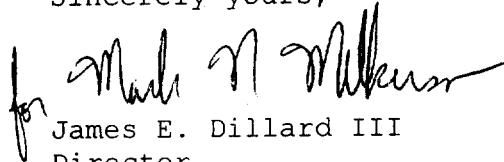
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. JoAnn Wolf

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Mark N. Milken

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment B

Indications for Use Statement

510(k)
Number

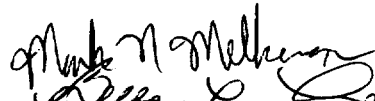

K002365

Device Name

Datascope's Reinforced Catheter Introducer Set

Indications
for Use

Datascope's Reinforced Catheter Introducer Set is intended for the percutaneous introduction of Datascope's 8Fr. and 9.5 Fr. Intra-Aortic Balloon Catheters.

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K002365

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CCRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____